



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,068	01/28/2004	Soichi Saito	WAKAB85.001AUS	2422
20995 7590 05/05/2009 KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			EXAMINER OLSEN, KAJ K	
			ART UNIT 1795	PAPER NUMBER
			NOTIFICATION DATE 05/05/2009	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
eOAPilot@kmob.com

Office Action Summary	Application No. 10/766,068	Applicant(s) SAITO ET AL.	
	Examiner KAJ K. OLSEN	Art Unit 1795	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 13-22 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-11 and 14-20 is/are allowed.
- 6) ☒ Claim(s) 21 and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

1. The amendment filed 1/30/2009 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: Applicant's changing of the word "lead" to --reed-- would appear to change the scope of the original disclosure. Applicant deemed this change a correction of a clerical error. The examiner tentatively does not agree. There was nothing clerically wrong with the term "lead" nor is it obvious from the original disclosure that the term "lead" should have been --reed-- instead (i.e. "lead" is not an obvious misspelling of "reed"). Hence, the examiner deems this change to be new matter. The examiner does note that because this disclosure is based on a foreign application, applicant could in theory establish that the specification actually said "reed" instead of "lead" based on the original foreign language disclosure (see MPEP 2163.07 (II)). In particular, applicant could explain which character in the original Japanese disclosure referred to the reed switch and provide a definition of that character establishing that "reed switch" is an appropriate translation of the character. Only then the examiner would potentially be in a position to deem this change to be an obvious error. Absent that, applicant would be required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

Art Unit: 1795

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 21 and 22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

4. New claims 21 and 22 appear to lack enablement for the same reasons as claims 12 and 13 did in the previous office action. Although applicant's change of "lead" to --reed-- would appear to indicate that the switch is indeed for position determination and not sensor response as the examiner speculated earlier, because applicant doesn't appear to have support for this change at this time, the originally filed disclosure doesn't support for a system for detection that the chemical sensor is installed in a position where it is immersed in a buffer solution.

5. New claims 21 and 22 also have a limitation drawn to no bias being applied across the working and reference electrodes during the step of immersing. Applicant does not appear to have any support for this limitation. In particular, the specification does not appear to have ever stated that no bias is to be applied to the electrodes, let alone no bias particularly during a set of immersing by the system for detection.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

Art Unit: 1795

such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Inamoto et al (USP 5,352,349) in view of Cozzette et al (USP 5,112,455) and Neel et al (USP 6,743,635). Neel is being cited and relied on for the first time with this office action. Its use was necessitated by the applicant's new claims.

8. With respect to claim 21, Inamoto discloses a chemical sensor type measuring apparatus (col. 1, ll. 11-21) comprising: a chemical sensor (see figs. 1,2 and 6) having at least a working electrode (1) and a reference electrode (2); a signal detection circuit (see figs. 1 and 6) including at least means for applying a bias (7, 7a, 7b, 6a, 5a, 5, 4, 12) between the working electrode and the reference electrode (col. 7, ll. 19-20 and col. 9, ll. 47-61), and a system detecting a signal measured by the chemical sensor (col. 9, ll. 19-25). Inamoto does not explicitly disclose the presence of a notification means to provide an indication that the chemical sensor is ready to be used. However, Cozzette teaches that it was known to utilize a notification device (i.e. display) to alert a user of the status of the sensor (see fig. 7-9 and col. 12, ll. 56-60, col. 13, l. 68 - col. 14, l. 2 and col. 16, ll. 60-68). It would have been obvious to one of ordinary skill in the art to have included the notification device as taught by Cozzette in the apparatus of Inamoto because it helps alert users of the apparatus of spikes, glitches, noise or observed values falling outside an expected range while using the apparatus as explained by Cozzette. With respect to this notification device being controlled by software, Cozzette teaches that the various processes of the notification means should be *automatic* (col. 13, ll. 62, 64, and 68) and software would be an obvious means for automatically controlling the processes of the notification means. With respect to the notification means being ready for measurement only after the set forth initial

Art Unit: 1795

treatment process has been performed, the particulars of the treatment process do not further define the actual notification means itself but merely state what process is to precede the notification.

9. Inamoto also does not explicitly disclose the presence of a system for detection that the chemical sensor is installed in a position where it is immersed in a buffer solution. With respect to the buffer solution, Inamoto does not specify what the sensor is immersed in during the pretreatment. However, because Inamoto only discloses applying the sample solution after the pretreatment (col. 11, ll. 66-68) (hence the pretreatment solution is not the sample solution) and because it discloses some solution containing hydrogen ions (fig. 4 and col. 8, ll. 9-27), it would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize a buffer for the pretreatment as suggested by Cozzette (col. 22, ll. 46-62) for apparatus of Inamoto because a buffer solution will closely mimic the buffering properties of blood, but also allowing the interfering species to be removed. With respect to the system for detecting, Neel, which is similar to the previous teaching of White, teaches that electrodes (28, 30) on a biosensor can be utilized to determine whether the electrochemical sensor is in contact with a solution (col. 8, ll. 4-17). This would read on the broadly defined system for detection of position of the sensor because this monitored current indicates that the biosensor has been solvated with a fluid whether the fluid be a sample solution or a buffer solution. Moreover, because the fill detect electrodes (28, 30) of Neel are separate from the working and reference electrodes, there is no requirement that a bias need be applied to the working and reference electrodes for the determination that the electrodes are immersed in the buffer (i.e. any bias would be across the fill electrodes and not the working and reference electrodes). It would have been obvious to one of

Art Unit: 1795

ordinary skill in the art at the time the invention was being made to utilize the teaching of Neel for the apparatus of Inamoto and Cozzette because the system of Neel is a simple means for ensuring that the sensor is appropriately solvated with fluid before performing the suite of voltage pulses disclosed by Inamoto.

10. With respect to claim 22, this claim appears to differ from claim 21 in only specifying that the first and second initial treatment steps are first and second refresh steps. This would not appear to change the scope of the claims because the actual contents of the treatment step in claim 21 were deemed to not further limit the actual apparatus. Moreover, whether the treatment of Inamoto in view of Cozzette and Neel is during an initial stage of the sensor or during a refresh stage is presumably only a function of whether the sensor is a new or old sensor. The claims make no distinction about the sensor and the terms “initial” and “refresh” would carry no additional meaning.

Allowable Subject Matter

11. Claims 1-11 and 14-20 are allowed for the reasons set forth in the 4/11/2008 office action.

Response to Arguments

12. Applicant's arguments with respect to claims 12 and 13 have been considered but are moot in view of the new ground(s) of rejection.

Art Unit: 1795

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAJ K. OLSEN whose telephone number is (571)272-1344. The examiner can normally be reached on M-F 5:30-2:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam X. Nguyen can be reached on 571-272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1795

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kaj K Olsen/
Primary Examiner, Art Unit 1795
May 1, 2009